

## REMARKS

Specification paragraphs [0005], [0026] and [0030] and claims 2, 3, 9, 17, 18, 22, 28, 29, 33, 34, and 36 have all been amended to delete the phrase "open end" and insert therefor the phrase "access end". This change renames the feature to employ a more appropriate term and is not to limit the claims and is not responsive to any rejection.

Claim 10 has been amended to eliminate the term "living" associated with the recitation of a hinge. The change is intended to broaden the claim as the type of hinge does not provide a distinction over the art presently presented. There are forty rejected claims; and claims 41 through 43 are added here.

Claim 1 was rejected in the Official Action mailed February 18, 2004 under 35 U.S.C. 102 as anticipated by Miller, U.S. Patent No. 4,944,397. Claims 2 through 40 were rejected under 35 U.S.C. 103 as obvious over Miller in view of Opalek (U.S. Patent No. 5,405,332). Several of claims 1 through 40 have been amended as noted above. None of the claims have been amended to overcome the rejections.

Turning to the rejection of claim 1, the U.S. PTO has recognized a standard by which rejections of anticipation are to be measured, set forth in MPEP §2131

Anticipation:

**TO ANTICIPATE A CLAIM, THE REFERENCE MUST TEACH EVERY ELEMENT OF THE CLAIM**

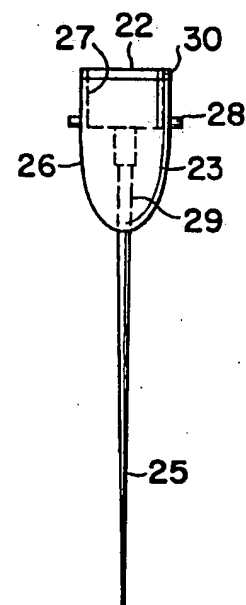
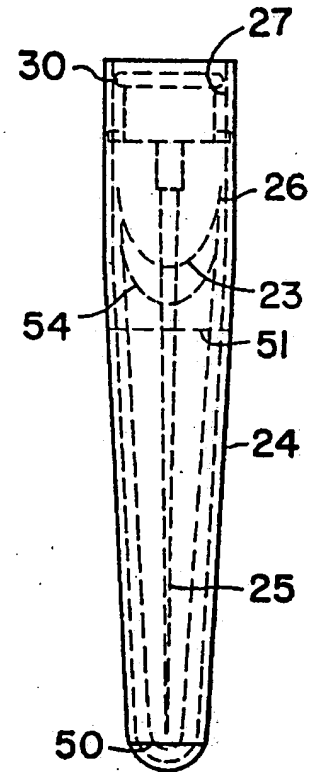
"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). The elements must be arranged as required

by the claim, but this is not an ipsissimis verbis test, i.e., identity of terminology is not required. In re Bond, 910 F.2d 831, 15 USPQ2d 1566 (Fed. Cir. 1990).

Claim 1 of the present invention includes a cover which has "a retainer engageable with the needle assembly with the elongate channel positioned over the needle" and a mount including "a socket to rigidly retain the luer hub of the needle assembly". Further, a hinge mounts the cover to the mount. Thus, there is the retainer of the cover, the socket of the mount and the hinge between the cover and mount.

In Miller, the pivot pins 28 hinge the cover member 24 and the needle member 23. The needle member 23 mounts the needle 25. There is no “retainer engageable with the needle assembly” that is part of the cover member 24. Further, the socket of the mount in claim 1 of the present application is recited “to rigidly retain the luer hub of the needle assembly.” The needle member 23 of Miller does not provide any such socket to retain a luer hub.

In view of the standard regarding anticipation, a *prima facie* case against claim 1 cannot be supported by Miller. As presented in the foregoing comparison, Miller lacks a retainer as part of a cover to engage the needle assembly and lacks a socket to retain a luer hub. Not every element of claim 1 is taught in Miller. Consequently, reconsideration of the rejection of claim 1 under 35 U.S.C. 102 over



Miller is earnestly solicited.

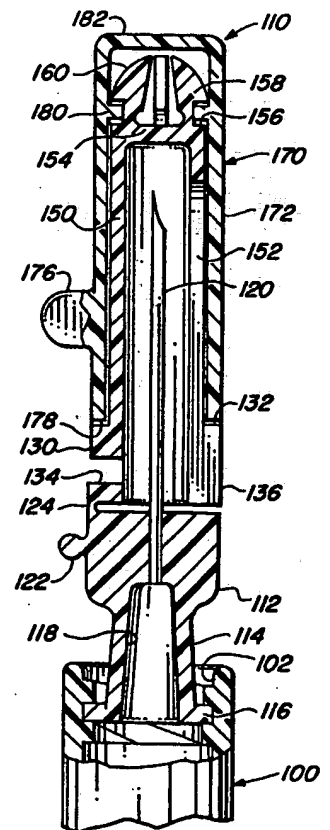
Turning to the rejection under 35 U.S.C. 103 of claims 2 through 40 over Miller and Opalek, the U.S. PTO has established the standard for a *prima facie* case of obviousness in MPEP § 2142, which states in part:

#### ESTABLISHING A *PRIMA FACIE* CASE OF OBVIOUSNESS

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. In *re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). See MPEP § 2143 § 2143.03 for decisions pertinent to each of these criteria.

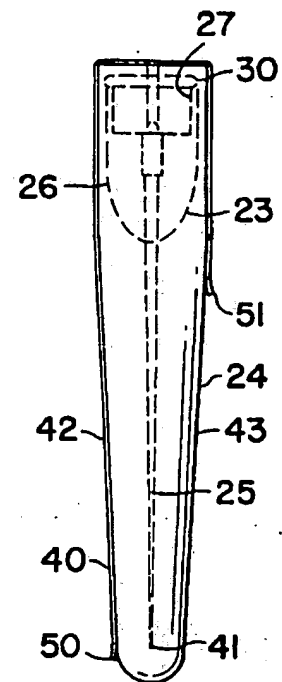
The foregoing discussion regarding anticipation is applicable to the issue of obviousness as the third requirement for a *prima facie* case has not been met with regard to claims 1 through 9 and 12 through 40. Opalek neither teaches nor suggests a retainer associated with a cover 150 engageable with the needle assembly 118, 120 separate from the mounting of the needle assembly 118, 120 in the lower base 112. As such, a *prima facie* case of obviousness cannot be made out against any of claims 2 through 9 and 12 through 40 because there is a claim recitation applicable to each which is not satisfied by either applied reference. The standard recognized in the MPEP cannot be met by the references.

Further, the relationship of the cover, the mount and the hinge in



the associations with the needle assembly as recited in all of claims 2 through 9 and 12 through 40 in the present application provides advantage not found in Miller and Opalek, taken independently or in combination. The retainer engageable with the needle assembly with the elongate channel positioned over the needle acts to retain the cover relative to the needle assembly. Maintaining the needle in free space before use rather than against a dulling surface provides benefit, particularly to the injectee.

Continuing to look at the third requirement in the standard for a *prima facie* case of obviousness, claims 3, 9, 18, 22 through 25, 29, 34 and 36 through 40 recite an end piece across the access end and a frangible sealing web between the mount and the end piece. This feature seals the needle assembly within the end of the mount prior to use. Miller discloses a tape 40 extending from 50 to 51 to seal the end and open slits down two sides of the cover member 24. Opalek does not disclose or suggest any mechanism for closing off the access end of the lower base 112. Therefore, the only mechanism disclosed is the tape 40 in Miller. The tape 40 does not close the needle member 23 for the needle assembly 25. It covers the cover member 24. The tape 40 does not define a frangible sealing web between the tape 40 and the needle member 23 but is directly connected to the cover member 24. There is no end piece and no frangible sealing web between an end piece and the mounting for the needle assembly. Again, the third requirement for a *prima facie* case of obviousness as established by the U.S. PTO cannot be met by these references for the aforementioned claims.



This detail of the end piece and frangible sealing web is of consequence. The end piece and web of the aforementioned claims provide a rigid closure on the mount. They allow the mount to be exposed and yet sealed before use. The mount can be held, manipulated and assembled with a syringe. In Miller, the mount (needle member 23) is within the cover member 24. without apparent direct access. One also doubts the integrity of the tape 40 extending about three sides of the cover member 24 as well.

Referencing the same element of the standard in the MPEP required to establish a *prima facie* case of obviousness, claims 4, 5, 10 through 15, 19 through 21, 23 through 25, 30, 31 through 35 and 38 through 40 all recite the presence of a frangible locking web between the cover and the mount. A careful review of Miller and Opalek establish that there is no locking web, frangible or not. In the Official Action mailed February 18, 2004, reference is made to elements 176 and 122. Element 176 is a rotation tab (col. 8, line 61 et seq.) which gives purchase to overcome the serrations to rotate the cylindrical cover 170 (col. 9, line 9 et seq.). It is a handle. Element 122 is a locking pin which engages a locking slot or recess 134 (col. 8, line 11 et seq.). Nothing is frangible and there is no web in this pin-and-slot mechanism. Albeit the living hinge 36 in Opalek could be considered a web in a broad sense, where then is the hinge as recited in the aforementioned claims?

The frangible locking web of the aforementioned claims employed in the present embodiment to establish a seal between the cover and the mount through a portion of the space therebetween is of consequence. As with the end piece and frangible sealing web discussed above with regard to other claims, the frangible locking web allows the mount to be exposed and yet sealed before use. The mount can be held, manipulated and assembled with a syringe. Again, the third requirement for a *prima facie* case of

obviousness as established by the U.S. PTO cannot be met by these references for the aforementioned claims. No such function is contemplated or discussed by either Miller or Opalek and no such sealing is in keeping with the structure of these devices.

As each of the missing features inconsistent with either reference is of significance in ways not contemplated by either reference, there is no teaching, suggestion or impetus to combine Miller and Opalek without hindsight consideration of the current application and claims. Miller forms a sealed cavity for the mount (needle member 23) entirely from the cover member 24 and the tape 40. Opalek does have the needle mount (lower base 112) exposed but doesn't try in any way to seal either end. The approaches are different and incompatible. Nothing would lead one of skill in the art in these teachings to the recited features in the above enumerated claims. Thus, the first requirement for a *prima facie* case of obviousness has not been satisfied as applied to all obviousness rejections.

From the foregoing, all rejected claims under 35 U.S.C. 103 have been discussed as to missing elements. One or more of the retainer, the end piece and web and the frangible locking web are found in claims 2 through 40. These elements are not found in Miller or Opalek, taken independently or in combination. A *prima facie* case of obviousness cannot be based upon these references.

New independent claim 41 includes a plurality of the recitations discussed above. Claim 41 specifically addresses the complete sealing by integrated means of the needle assembly with access to both the cover and the mount. No thought is given to this concept of complete sealing in either of Miller or Opalek.

In view of the careful examination of the several recitations in rejected claims 1 through 40, it can be found that neither Miller nor Opalek teach or suggest these

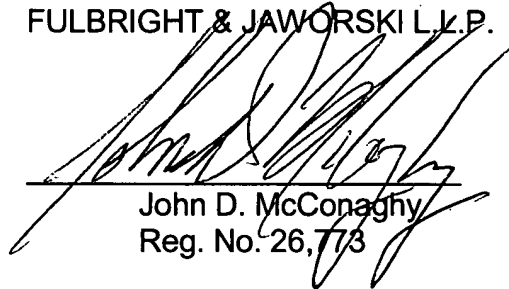
recitations. As such, *prima facie* cases of anticipation and obviousness cannot be supported from these references. Accordingly, a Notice of Allowance is earnestly solicited.

Respectfully submitted,

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